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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,681	02/01/2001	Linda A. Sherman	313332000101	3045

21874 7590 01/24/2002

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EXAMINER
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WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 01/24/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicant(s)

09/774,681

Applicant(s)

SHERMAN ET AL.

Examiner

Michael Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 6-21 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*

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### **DETAILED ACTION**

It is noted that the marked up version and clean copy of the amendment filed 9-4-01, paper number 10, differ. The clean copy amends claim 12 and the marked up version incorrectly states claim 5. Claim 12 has been amended as the text of the claim is not found in claim 5. Please review future amendments carefully for accuracy.

Claims 1-5 have been canceled. Claims 6-21 are pending in the instant application.

### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 6-19, drawn to nucleic acids and recombinant cells, classified in class 536, subclass 23.1.
- II. Claim 20, drawn to a method of identifying TAAs, classified in class 435, subclass 70.1+.
- III. Claim 21, drawn to a method of gene therapy, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions in Group I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the

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instant case the DNA encoding TCRs specific for TAA in Group II can be identified and isolated using tumor cell lines and T-cells isolated from cancer patients and grown *in vitro*.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Groups I and III are unrelated because the method of identifying nucleic acids encoding a TCR using a transgenic animal can be used to isolate nucleic acids encoding TCRs while the method of identifying a TAA can be used to classify tumor types. The method of identifying nucleic acids encoding TCRs does not require identification of cell surface antigens such as TAA. The method of identifying cell surface TAAs does not require identification of nucleic acids encoding TCRs. The reagents and protocols required to identify and isolate nucleic acids are materially distinct and separate from methods of determining cell surface markers such as TAAs.

Groups I and IV are unrelated because the method of identifying nucleic acids encoding a TCR using a transgenic animal can be used to study T-cell response to tumor antigens while a method of administering a gene is for therapy. The method of identifying nucleic acids encoding a TCR does not require a method of gene therapy and a method of gene therapy does not require identifying a nucleic acids encoding TCR. The reagents and protocols required for each method are materially distinct and separate.

Groups II and III are unrelated because the nucleic acids and recombinant cells can be used to make protein while the method of identifying TAA can be used to study tumor

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immunology. The nucleic acids and recombinant cells do not require identification of TAA and the method of identifying TAAs does not require nucleic acids and recombinant cells. The reagents and protocols required to make nucleic acids and recombinant cells are materially distinct and separate from those used to identify TAA.

Groups II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA can be used to make protein, to make probes or for gene therapy.

Groups III and IV are unrelated because the method of identifying TAA can be used to study tumor biology while administering DNA can be used as a treatment for cancer. The method of identifying TAA does not require gene therapy and gene therapy does not require identification of TAA. The reagents and protocols required to identify TAA are materially distinct and separate from those used for gene therapy.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and the search required for Groups I-IV are not required for each other, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).


Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-2982.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.  
Michael C. Wilson

  
MICHAEL C. WILSON  
PATENT EXAMINER